

A Novel Inline PEEP Valve Design for Differential Multi-Ventilation

Leonard Bunting MD¹, Steven Roy MD², Hannah Pinson³, Tobin Greensweig MD⁴ on behalf of the International Differential Multi-Ventilation Working Group⁵

¹Wayne State University, Detroit, Michigan; Department of Emergency Medicine, Ascension Providence, Southfield, Michigan

²Department of Critical Care Medicine, University of Calgary, Calgary, AB

³Applied Physics/Data Analytics, Vrije Universiteit, Brussels, Belgium

⁴Department of Critical Care Medicine, Indiana University School of Medicine, Indianapolis, Indiana

⁵See Appendix for membership

Corresponding Author:

Leonard Bunting, MD

Department of Emergency Medicine

Ascension Providence Hospital

16001 W 9 Mile Rd Southfield, MI 48075

Leonard.Bunting@ascension.org

Phone: 248-420-7680

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Appendix included here to keep manuscript blinded:

APPENDIX

International Differential Multi-Ventilation Working Group (www.differentialmultivent.org)

Contributing Members:

Arun Agrawal MD, Columbia, Missouri

James O'Neal, Columbia, Missouri

Nate Surls, Indianapolis, Indiana

Full Membership:

Lucas Caesens, Ghent, Belgium

Gert-Jan Gysemans MD, Leuven, Belgium

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Stephen Gordon, New Orleans, USA
Simran Kaur Matta MD, Dover, USA
Grégoire Le Brun, Louvain-La-Neuve, Belgium
Albert Lee MD, Los Angeles, California
Matthew Levin MD, New York, New York
Tormod Martinsen, Oslo, Norway
Matthias Mergeay MD, Geel, Belgium
Kate Price Thomas, Cambridge, UK
Ellen Roels, Brussels, Belgium
Jean Ruwet MD, Thimister, Belgium
Anjan Shah MD, New York, New York
Stefan Stahl, Zurich, Switzerland
Dominik Textor, Zurich, Switzerland
Christian Tronstad, Oslo, Norway
Dirk Van Nieuwenhove, Aalst, Belgium
Tom Vrysen, Pelt, Belgium

ABSTRACT

BACKGROUND

Ventilator sharing is one option to emergently increase ventilator capacity during a crisis but has been criticized for its inability to adjust for individual patient needs. Newer ventilator sharing designs use valves and restrictors to control pressures for each patient. A key component of these designs is an inline Positive End Expiratory Pressure (PEEP) Valve but these are not readily available. Creating an inline PEEP valve by converting a standard bag-valve-mask PEEP valve is possible with the addition of a 3D printer collar.

METHODS

This was a feasibility study assessing the performance and safety of a method for converting a standard PEEP valve into an inline PEEP valve. A collar was designed and printed that covers the exhaust ports of the valve and returns exhaled gases to the ventilator.

RESULTS

The collar piece was simple to print and easily assembled with the standard PEEP valve. In bench testing it successfully created differential pressures in 2 simulated expiratory limbs without leaking to the atmosphere at pressures greater than 60 cm of H₂O.

CONCLUSION

Our novel inline PEEP valve design shows promise as an option for building a safer ventilator sharing system.

INTRODUCTION

One of the greatest challenges facing clinicians during the COVID-19 pandemic is the overwhelming number of patients requiring ventilatory support. Hospitals in some areas have already faced having more patients that require mechanical ventilation than their available supply.

One proposed method to extend the ventilator supply is to share a single ventilator between 2 or more patients. Following its initial development in 2006¹, investigations into ventilator splitting were initially limited to simulation² and an animal study³. More recently, experience using shared ventilation in human patients has emerged from New York where a form of the technique was successfully applied to treat multiple patients with COVID-19 in the face of ventilator shortages.

Ventilator splitting has received crisis approval by Health and Human Services and the Federal Drug Administration during the COVID-19 pandemic⁴. However, it has also received criticism and words of caution from several preeminent medical organizations⁵. One of the concerns of these groups is the inability to adjust ventilator settings for patients individually to compensate for changes in patients' clinical status.

To address these concerns, several groups have been working to create modified ventilator circuits which permit individualized settings for patients sharing a ventilator also known as Differential Multi-Ventilation (DVM). These systems utilize valves, sensors, and restrictors to allow for discrete adjustment and monitoring of ventilation parameters. A key component of these systems is an inline Positive End Expiratory Pressure (PEEP) valve. With the ventilator in a pressure control mode, which is recommended for DVM setups^{1-4,6}, a pressure relief type valve like an inline PEEP valve allows for adjustment of individual inspiratory and expiratory pressures. When placed on the expiratory limb, they allow for increased PEEP above the ventilator. When placed on the inspiratory limb, they remain closed to ventilator pressure until their setpoint is reached, thereby decreasing the inspiratory pressure, and therefore volume, delivered to the patient.

Adjustable inline PEEP valves are commercially available, but have been consistently backordered since the start of the pandemic and are not commonly stocked in hospitals. Standard adjustable PEEP valves are commonly available and used on bag-valve-masks during resuscitation; however, these models vent exhaled gases to the atmosphere whereas inline valves keep all gas within the circuit. The latter is preferable because most ventilators detect leak by comparing the volume of air returning from the expiratory limb to the volume delivered to the inspiratory limb. Venting to the atmosphere will result in the ventilator detecting a leak, and has the potential to contaminate providers and other patients.

If a commercial inline PEEP valve is not available, a standard PEEP valve can be converted to an inline version with the addition of a device that collects exhaled gases. The authors, in conjunction with the International Differential Multiventilation Working Group (www.differentialmultivent.org), propose a novel 3D printed collar that fits a standard bag-valve-mask (BVM) PEEP valve and converts it to an inline valve.

METHODS

IMAGE 1: A- a standard bag-valve-mask (BVM) PEEP valve (a) adjustment cap, (b) valve stem, (c) exhaust vents; B- a proposed diagram of the valve with the 3D-printed Collar; C- picture of the prototype

A standard BVM PEEP valve is an adjustable pressure relief valve (Image 1, A). It has a diaphragm held in place by a spring which separates the pre- and post-valve airflow. The diaphragm opens to allow air to pass when the pre-valve pressure exceeds the setpoint of the valve. The valve setpoint is adjusted by turning a knob on top of the valve, which loads the spring and increases the pressure required to open the diaphragm. However, a standard PEEP valve vents exhaled air to the atmosphere. To convert this to an inline valve, the authors designed a collar that sits on the exhaust side of the valve and collects exhaled gasses to return them to the ventilator. The device is printable with professional or hobbyist level 3d printers. Construction after that takes just a few minutes.

Design: measurements were taken of all available PEEP valves. Using Tinkercad 3D design software (www.tinkercad.com), a collar was designed with one end that slipped over the neck of the PEEP valve to cover the outflow and an outflow tube that connected to standard 22mm ventilator tubing (Image 1, B).

Construction: The collar was printed with 1.75mm PETG filament (240° C nozzle, 70° C bed, 40% infill) on a Creality (Shenzhen, China) Ender 3 printer. A standard BVM PEEP valve was obtained (Teleflex Medical- Morrisville, NC). The valve adjustment cap was unscrewed and removed and the set screw (if present) was removed from the cap. The collar was slid over the PEEP valve and a small amount of sealant (eg epoxy or silicon) was applied over the upper and lower joints of the collar to the valve. Thread sealing tape (aka plumbers tape) was wrapped around the threads of the PEEP valve prior to screwing the cap back on (Image 1, C).

FIGURE 1: Diagram of testing setup – (A) air compressor, (B&D) manometers for measuring circuit pressure, (C) novel collared PEEP valve, (E) Second PEEP valve

Testing: the collared valve (Figure 1, C) was setup in series with another PEEP valve (Figure 1, E) to simulate it being used with a ventilator. Simple manometers were constructed to measure the pressure behind Valve C (i.e. the PEEP delivered to a patient) and behind Valve E (i.e. the PEEP set on the ventilator). Pressure testing for valve leaks was done by submerging the valve in shallow water and observing for air bubbling.

RESULTS

TABLE 1: Pressures measured before Valve 1 (collared valve) and Valve 2 (simulating ventilator PEEP) resulting from changes in valve setpoints. All pressures in cm H₂O.

Our prototype successfully increased the PEEP delivered to one side of the system without affecting the other (Table 1). With the collared valve 1 set at 5cm H₂O and Valve 2 set to 5cm of H₂O, the total pressure before the collared valve was 10 and the pressure before valve 2 remained 5cm of H₂O.

To test the integrity of the valve, it was pressure tested. When operating as a single valve, the collared valve was able to hold up to 12.5 cm of H₂O of pressure without leaking from around the valve stem. When a second valve was connected in series, a total PEEP of 32 cm of H₂O was achieved but the valve began to leak from around the cap even with small amounts of back pressure. The valve cap was removed, 7 wraps of joint thread tape was applied to the threads of the valve and the cap was rethreaded on the valve. On re-testing, the valve no longer leaked up to 61 cm of H₂O, which was the maximum test pressure of the manometer.

DISCUSSION

Ventilator splitting is a method to share a single ventilator between multiple patients. This practice is reserved for crisis situations when there are insufficient ventilators to meet demand. Unfortunately, during the beginning of the COVID-19 pandemic in New York this situation occurred, and multiple patients had to share ventilators. Given the safety concerns about the inability to individualize ventilation parameters during ventilator sharing, improvements in ventilator splitting design are crucial.

Our prototype collar successfully converts a standard bag-valve-mask PEEP valve to an inline PEEP valve. With this type of valve, a split ventilation system can be built with different PEEP settings for each patient. For example, one patient can receive a PEEP of 5 cm of H₂O set at the ventilator while the other patient receives a total PEEP of 10 after having an inline PEEP valve like ours set to 5 cm of H₂O inserted into their expiratory limb. A check valve on the inspiratory limb would also be inserted on the same side as the PEEP valve to prevent back-flow of the higher expiratory pressure into the other patients' lower pressure system.

Our valve did not leak when there was no back pressure, which is simulating a situation where the ventilator PEEP was set to 0. However, with back pressure the valve stem seal began to leak. Although this was solved by the addition of thread tape, this is not an ideal solution. If further testing determine this collared valve is suitable for clinical use, it would be safest to keep the ventilator PEEP at 0 and use collared PEEP valves on each patients' expiratory limb to adjust individual expiratory pressures. In this situation the authors still recommend thread sealing tape as a backup safety measure.

Commercial valves would be preferred. However, as mentioned, they are not stocked in our hospital nor were adjustable ones available for purchase. In fact, insufficient commercial valves could be found to test differential multiventilation system designs. This lack of availability is what drove the authors to create alternatives.

3D-printed adjustable inline PEEP valve designs are available online. However, no data is available on their performance. There is also the variable quality between 3D printers and 3D prints to consider. As our design relies on an FDA cleared standard medical device, the valve itself is inherently reliable. The collar is 3D printed and therefore we recommend each valve be tested.

It is the authors' opinion that any 3D printed valve or adapter should be pressure tested prior to use. If unable to perform elsewhere, this can be performed in the hospital by connecting the device to any positive pressure ventilating machine (cpap, bipap, mechanical ventilator). Set the driving pressure to as high as possible (>40cm of H₂O at minimum) to simulate all stresses. Occlude the system to fully pressurize it and submerge the device in sterile water. If bubbling occurs the device should be discarded.

LIMITATIONS

Most importantly this is a prototype and has not been tested in animals or humans. Further testing is needed before it can be safely deployed. Aside from the issues with 3D printing listed above, the valve requires a small amount of sealant which could be a source of error. If not applied properly it could create an air leak or enter the valve chamber and effect valve function. This is part of the reason testing each item is crucial. The durability of the valve has not been tested and it may be more prone to cracking. The assembled collared valve would need to be cleaned and sterilized. Although not tested, plastic devices similar to this can be sterilized with non-heat methods such as used for endoscopes.

CONCLUSION

Inline PEEP valves are required to individualize ventilation parameters in a split ventilation setup. The authors present a novel inline PEEP valve based on a standard BVM PEEP valve. A 3D printed collar is sealed to the valve and collects exhaled gases to return them to the ventilator. With further testing our valve design could be used when commercial inline valves are not available.

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CREDIT AUTHOR STATEMENT

Leonard Bunting: Conceptualization, data collection, writing – original draft, correspondence, reviewer response

Tobin Greenweig: Conceptualization, writing – review and editing

Hannah Pinson: Writing – review and editing, organizer

Steven Roy: Conceptualization, figure creation, writing – original draft, review and editing

Valve 1 Set Pressure	Valve 2 Set Pressure	Pressure Pre-Valve 1	Pressure Pre-Valve 2
5	-	5	
10	-	7	
15	-	12.5	
5	5	10	5
10	5	15	5
12.5 (max setpoint)	5	17	5
12.5 (max setpoint)	10	22	10
12.5 (max setpoint)	20	32	22

TABLE 1: Pressures measured before Valve 1 (collared valve) and Valve 2 (simulating ventilator PEEP) resulting from changes in valve setpoints. All pressures in cm H₂O.